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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/067,146 | 02/04/2002 | Frederick P. Siegal | 10034-004 | 7266 |
| 1912 | 7590 | 07/08/2005 | EXAMINER | |
| AMSTER, ROTHSTEIN & EBENSTEIN LLP 90 PARK AVENUE NEW YORK, NY 10016 | | | KAUSHAL, SUMESH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| DATE MAILED: 07/08/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/067,146

Applicant(s)

SIEGAL ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1633

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 11,15,21-24 and 26-35.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.


**SUMESH KAUSHAL
PATENT EXAMINER**

Continuation of 11. does NOT place the application in condition for allowance because: Claims 11, 15 and 21-24, 26-30 and 32-35 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the same reasons of record as set forth in the office action mailed on 04/21/05.

Response to Arguments

Invention relates to a method of monitoring the progression of HIV infection or AIDS in a patient by measuring the number of pDC2 cells in lymphoid or blood sample obtained from the patient as compared to a control sample.

Applicant's arguments filed on pages 5-8 regarding enablement issues have been fully considered but they are not persuasive. Applicant's argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of skill. At best the specification discloses evaluation of IFN-production by total PBMCs or pDC2-depleted, pDC2-enriched mononuclear cells.

Regarding the age-related decline of IFN production by pDC2 cells the applicant argues that an age related control match is not required, since age related reduction in interferon levels in pDC2 cells occurs over decades and the reduction in interferon levels would not be evident in the relatively short three year time frame in the study disclosed in the spec. However this is found not persuasive because the invention as claimed is not limited to an age related control sample, which is considered germane to practice the instant invention. For example using a control sample from an older individual against an HIV infected young individual would provide an erroneous interpretation regarding the interferon production and number of pDC2 cells in the infected individual, suggesting HIV infection or AIDS is not progressing the infected individual.

Regarding inference of number of pDC2 cells based upon IFN production the applicants arguments has been found not persuasive because the specification fails to provide any correlation between the number of interferon units produced and number of CD4+, CD3-, CD11c- pDC2 cells, especially in view age-related variation. Similarly the specification as filed fails to establish any correlation between the number of pDC2-interferon-producing dendritic cells and the progression of HIV infection and/or AIDS

Regarding the phenotype of pDC2 cells applicants arguments has been found persuasive because the claims has been amended to recite wherein the pDC2 cells are CD4+, CD3-, CD11c-.